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K965087
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 **SANDOZ**

**APPENDIX E
510(K) SUMMARY**

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Submitter Name:

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December 9, 1996

Device Name :

Classification Name: Gastrointestinal Tube and Accessories (21 CFR 876.5980)
Common/Usual Name: Surgical Gastrostomy/Jejunostomy Feeding tube Kit.
Trade Name: Sandoz Nutrition COMPAT Surgical
Gastrostomy/Jejunostomy Feeding Tube Kit.

Identification of the Legally Marketed Device

The #088000 MODIFIED SURGICAL GASTROSTOMY/JEJUNOSTOMY FEEDING TUBE KIT is Substantially Equivalent (SE) to the currently marketed Sandoz Nutrition #088000 Surgical Gastrostomy/Jejunostomy Feeding Tube Kit currently marketed under K853351/A

Description of the device that is the subject of this 510(K).

A Surgical Gastrostomy/Jejunostomy Feeding Tube Kit.

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Office 5100 Gamble Drive **Manufacturing** 5320 West Twenty Third Street
Distribution 1551 Park Place Boulevard **Research and Development** 1541 Park Place Boulevard

Statement of intended use of the device.

The Sandoz Nutrition #0888000 Gastrostomy/Jejunostomy Feeding Tube is intended for use with patients who require delivery of enteral feeding formulas directly into the small bowel (jejunum). The Sandoz Nutrition #088000 Gastrostomy/Jejunostomy Feeding Tube is intended for use with patients who require enteral feeding. Indications for such medical and post-surgical treatments may include surgical problems, prolonged artificial ventilation, central nervous system trauma, and others. The placement of the device in patients is accomplished surgically using standard surgical techniques.

The Sandoz Nutrition #0888000 Gastrostomy/Jejunostomy Feeding Tube also provides for the evacuation of gastric contents through the gastrostomy tube while simultaneously feeding directly into the small bowel with the jejunal feeding tube.

Summary of technological characteristics in comparison to those of the predicate device.

1. **Intestinal feeding and gastric drainage.**

The Sandoz #088000 Surgical Gastrostomy and Jejunostomy Feeding Tube Kit provides the same ability as the comparative substantially equivalent (SE) device for delivery of formula and medications to the small intestine (through "FEED" port) while allowing simultaneous gastric drainage (through "DRAIN" port) via the gastrostomy tube.

2. **Placement techniques and confirmation methods.**

Initial placement of the #088000 Kit tubes may be accomplished surgically, as with the predicate SE device through a laparotomy midline incision and Stamm (gastrostomy) technique. The jejunal feeding tube can be placed in a similar fashion to that of the SE device in that the tube is led through the lumen of the gastrostomy tube into the stomach, then grasped at its tip and manipulated through the gastric pylorus into the small intestine.

This manual manipulation into the bowel is assisted by the presence of the bolus tip on the jejunal tube and by a removable stylet. **In the SE device, the stylet is a twisted wire stiffener; however, in the device of this submission, the stylet is made of a plastic material with an inflatable cuff/balloon at its distal end.** The inflation of the cuff provides an additional (temporary) feature for grasping and directing the jejunal tube tip.

Both the SE and modified (submission) devices contain a Y-port at the connector end of the Jejunal Feeding tube which may be pressed into the lumen of the Gastrostomy tube to complete the placement and allow for gastric drainage through the gastrostomy tube. The Gastrostomy/Jejunostomy tube combination may be immobilized using the external retainer and the abdomen may be closed in the standard fashion.



Confirmation of placement of both tubes may be accomplished using x-ray or fluoroscopic techniques.

3. **Tube and Stylet Construction.**

- The construction of the Gastrostomy and Jejunostomy tubes is **almost identical to that of the SE device** for the #088000 Kit. The only difference occurs in the Jejunal feeding tube where the **Y-Connector has been modified to a 3 part assembly** from what was previously an 8 part assembly. This revised Y-Connector assembly was included in a previous 510(k) notification, K961664. Also, the bolus tip is shortened.
- The two stylets of the SE device and the submission device differ in that:
 - a) The SE device stylet is a twisted wire construction with an end button.
 - b) The submission device stylet is a semi-rigid plastic tube with and inflatable cuff/balloon at one end and an inflation port/valve at the opposite end.

The applied standard for strength of bonding joints on portions of devices which will reside internally to a patient is the same as in the SE product.

Conclusions Drawn that demonstrate that the device is safe, as effective and performs as well as the legally marketed device.

Sandoz Nutrition believes that the changes described in this submission do not negatively affect the safety or effectiveness of the product. The material and bonding method for the gastrostomy and the jejunal feeding tubes are identical to those used in the SE device.

Indications for Use:

The **Sandoz Nutrition Surgical Gastrostomy/Jejunostomy Feeding Tube Kit** provides for the delivery of enteral formula through a surgically placed Gastrostomy/Jejunostomy feeding tube. Jejunal feeding is used when patients require feeding past the stomach directly into the jejunum. This method is used to enhance the absorption of nutrients and minimize the risks of gastric feeding including gastric reflux and aspiration.

